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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,573	07/11/2003	Ellen Filvaroff	P1381R1C1P4C1	8245

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EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
08/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/617,573	FILVAROFF ET AL.	
	Examiner	Art Unit	
	DONG JIANG	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *61,63-66,68,69,76-84 and 86* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *61,63-66,68,69,76-84 and 86* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/7/08, 6/3/08 & 7/16/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

The request filed on 15 November 2007 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 10/617,573 is acceptable, and a RCE has been established. An action on the RCE follows.

Applicant's amendment filed on 15 November 2007 is acknowledged and entered. Following the amendment, claims 70-75 and 85 are canceled.

Currently, claims 61, 63-66, 68, 69, 76-84 and 86 are pending and under consideration.

Information Disclosure Statement

The information disclosure statements filed 2/7/08, 6/3/08 and 7/16/08 are acknowledged, and have been considered. A signed copy is attached hereto.

Withdrawal of Objections and Rejections:

All objections and rejections of claims 70-75 and 85 are moot as the applicant has canceled the claims.

Rejections Over Prior Art:

The following rejections under 35 U.S.C. § 102 and 103 are made in view of the determination that the effective filing date for the instantly claimed invention is 10/30/01, which is the filing date of a prior application 10/000,157, and relied upon in the instant application for an earlier filing date under 35 U.S.C. 120 (see Office Action mailed on 8/14/06, pages 2-3).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 61, 63-66 and 76-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Medlock et al., US7,094,566 B2.

Medlock discloses an IL-17E ligand, which amino acid sequence of SEQ ID NO:23 comprises the amino acids 33-177 (the mature form) of the present SEQ ID NO:6 with 100% sequence identity, and is the ligand for the IL-17R like polypeptides IL-17RB-2 of SEQ ID NO:2 and IL-17RB-3 of SEQ ID NO:5 (column 6, lines 51-54). Additionally, Medlock teaches that IL-17E plays a role in inflammation, including autoimmune diseases (column 6, lines 44-46). Further, Medlock teaches methods of treating a pathological condition mediated by IL-17E with a molecule specifically binding to either IL-17E or the receptor polypeptides; and a method of inhibiting undesirable interaction of IL-17R like polypeptide with IL-17E using an inhibitor molecule including selective binding agents such as *antibodies* specific for either IL-17E specifically or the receptor polypeptides (column 7, lines 6-21). Furthermore, Medlock teaches that IL-17E mediated pathological conditions included but not limited to those conditions related to immune system dysfunction, inflammation including acute or chronic inflammation ... (column 7, lines 27-30), such as rheumatic diseases (column 53, lines 40-41). Furthermore, Medlock teaches a non-exclusive list of acute and chronic diseases which can be treated with the IL-17R like nucleic acids, polypeptides, and agonists and antagonists of the invention, including rheumatoid arthritis, psioriatic arthritis, osteoarthritis, inflammatory joint disease, … and inflammatory conditions resulting from cartilage damage … (column 48, line 65 to column 49, line 12).

Medlock does not explicitly mention the use of the IL-17E antibody (antagonist) for treating a degenerative cartilaginous disorder.

However, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to use the antagonist antibody to IL-17E for the treatment of a degenerative cartilaginous disorder such as rheumatoid arthritis, psioriatic arthritis, or osteoarthritis because Medlock teaches that IL-17E plays a role in inflammation, including autoimmune diseases, and mediates pathological conditions including acute or chronic inflammation such as rheumatic diseases; and that an inhibitor molecule such as an antibody specific for either IL-17E or its receptor polypeptides would inhibit undesirable interaction of IL-17R like polypeptide with IL-17E. The person of ordinary skill in the art would have been motivated to make that Medlock teaches that an inhibitory antibody for IL-17E could inhibit undesirable interaction of IL-17R like polypeptide with IL-17E.

Claims 68 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Medlock et al., US7,094,566 B2 as applied to claims 61, 63-66 and 76-79 above, and further in view of Coligan et al. (Current Protocols in Immunology, 1991, pages 2.5.1 to 2.5.17).

The teachings of Medlock are reviewed above. The primary reference does not specifically teach the use of a monoclonal antibody to the polypeptide for the treatment.

Coligan disclose a method of producing monoclonal antibodies, and teaches that monoclonal antibodies have high specificity and can be produced in large quantities (page 2.5.1, the first paragraph).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to obtain a monoclonal antagonist antibody to IL-17E polypeptide disclosed by Medlock following the method taught by Coligan, and to use the monoclonal antibody for the treatment of the degenerative cartilaginous disorders as indicated by Medlock. The person of ordinary skill in the art would have been motivated to use the monoclonal antibody for the known and expected advantages of such an antibody as taught by Coligan, reasonably would have expected success because Coligan's method of producing monoclonal antibodies has been well established and widely used in the art.

Claims 69 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Medlock et al., US7,094,566 B2 as applied to claims 61, 63-66 and 76-79 above, and further in view of Kucherlapati et al. (US6,075,181).

The teachings of Medlock are reviewed above. The primary reference does not specifically teach the use of a human antibody to the polypeptide for the treatment.

Kucherlapati teaches a method of producing fully human monoclonal antibodies to any protein of interest by using the protein to immunize mice, which express human antibody genes (see entire document, but especially columns 8-9). Further, Kucherlapati teaches that fully human monoclonal antibodies are highly advantageous compared to rodent antibodies or even humanized antibodies for therapeutic applications, because administration of human antibodies to humans avoids the undesired immune responses elicited by administering non-human antibodies to humans (see column 8, lines 21-41).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to obtain a human antibody to IL-17E polypeptide disclosed by Medlock following the method taught by Kucherlapati, and to use the human antibody for the treatment of the degenerative cartilaginous disorders as indicated by Medlock. The person of ordinary skill in the art would have been motivated to do so for disease treatment, and for the advantage of a human antibody in therapeutic application in comparison to the other types of antibodies, as taught by Kucherlapati; and reasonably would have expected success because Kucherlapati has demonstrated successfully the production of human antibodies to multiple proteins including IL-6, IL-8 and TNF-α.

Claims 82-84 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Medlock et al., US7,094,566 B2 as applied to claims 61, 63-66 and 76-79 above, and further in view of Sandhu (Critical Reviews in Biotech., 1992, 12(5/6): 437-462, especially pages 443-450).

The teachings of Medlock are reviewed above. The primary reference does not specifically teach the use of a humanized or chimeric antibody to the polypeptide for the treatment.

With respect to claim 82, Sandhu teaches that the major obstacle in the clinical application of murine monoclonal antibodies is the immunogenicity of the C region, that to solve this

problem, Bouliane et al. developed a technique to make murine (V)/human (C) chimeric antibodies (page 444, 1st column, lines 1-5), and that in human therapy, the HAMA response has been reduced greatly by the use of chimeric antibody (page 445, 2nd column, lines 16-18 of the second paragraph). Further, with respect to claim 83, Sandhu teaches humanized antibodies, which would further reduce the immunogenicity of the variable domains caused by species difference (the paragraph bridging pages 444 and 445). Furthermore, with respect to claims 84 and 86, Sandhu teaches Fab and Fv fragments of an antibody, and indicates that small antibody fragments, such as Fv, may have important applications in the diagnosis and treatment of tumors, where their small size may allow greater penetration, and are ideal for structural studies and in vivo imaging (page 449, the last paragraph of the right column), and that single chain Fv fragments have the main advantages of their rapid clearance from human circulation and reduced toxic side effects (page 450, F).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to obtain a chimeric or humanized antibody, or antibody fragments such as Fab and Fv to IL-17E polypeptide disclosed by Medlock following the teachings by Sandhu, and to use them for the treatment of the degenerative cartilaginous disorders as indicated by Medlock. The person of ordinary skill in the art would have been motivated to do so for disease treatment, and for the advantage of the chimeric or humanized antibody, or the antibody fragments in therapeutic application in comparison to the other types of antibodies, as taught by Sandhu; and reasonably would have expected success because Sandhu has demonstrated such antibodies and antibody fragments.

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on 9:30 am - 7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dong Jiang/
Primary Examiner, Art Unit 1646
8/6/08